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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,586	06/19/2001	Yann Echelard	10275-120001 / GTC-31 US	2580

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	13

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,586	ECHELARD ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-31 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 11-12 and 14-15, drawn to methods of producing a transgenic mammal capable of expressing an active PDGF molecule in its milk comprising introducing into an oocyte a nucleic acid sequence encoding PDGF chains or PDGF B chain or nucleic acid sequences encoding PDGF A chain and PDGF B chain; and a method of producing platelet derived growth factor using the same transgenic mammal, classified in class 800, subclass 25.

II. Claims 1-8, 10-11, 13-14 and 16, drawn to methods of producing a transgenic mammal capable of expressing an active PDGF molecule in its milk comprising introducing into a somatic cell a nucleic acid sequence encoding PDGF chains or PDGF B chain or nucleic acid sequences encoding PDGF A chain and PDGF B chain, and the somatic cell or the nucleus of the somatic cell is introduced into an oocyte; and a method of producing platelet derived growth factor using the same transgenic mammal, classified in class 800, subclass 24.

III. Claims 17-24, drawn to a milk preparation obtained from a transgenic mammal whose genome contains a nucleic acid sequence encoding at

least one PDGF chain operably linked to a promoter which directs expression in mammary epithelial cells, wherein the PDGF chain is expressed in the mammary epithelial cells of the transgenic mammal and wherein at least 30% of the PDGF in the milk is present as a dimmer, classified in class 426, subclass 580.

IV. Claims 25-31, drawn to an isolated nucleic acid comprising nucleic acid sequence encoding a biologically active PDGF or a homolog thereof operatively linked to a regulatory sequence capable of directing the expression of PDGF in the mammary gland of non-human transgenic mammals, classified in class 435, subclass 320.1.

Claims 8, 11 and 14 link a plurality of the above patentably distinct methods of producing a transgenic mammal capable of expressing an active PDGF molecule in its milk of Groups I and II that lack the unity of invention. This is because the methods of producing the transgenic mammal involve different starting materials, method steps and different technical considerations for attaining the transgenic mammal. For example, the method of Group I requires the introduction of a nucleic acid sequence encoding PDGF chains into an oocyte, whereas the method of Group II requires the introduction of a nucleic acid sequence encoding PDGF chains into a somatic cell, then the somatic cell or the nucleus of the somatic cell is introduced into an oocyte. The methods of Groups I and II can be carried out independently one from the other. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being

essential to that utility. Thus, claims 8, 11 and 14 are improper written as linking claims linking multiple distinct inventions. Applicant is required under 35 U.S.C. 121 to elect the invention of Group I or Group II.

The restriction requirement between linked inventions is subject to the non-allowance of the linking claims 8, 11 and 14.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because the methods in Groups I and II appear to constitute patentably distinct inventions for the same reasons already stated above. Basically, these methods of producing the transgenic mammal involve different

starting materials, method steps and different technical considerations for attaining the transgenic mammal. For example, the method of Group I requires the introduction of a nucleic acid sequence encoding PDGF chains into an oocyte, whereas the method of Group II requires the introduction of a nucleic acid sequence encoding PDGF chains into a somatic cell, then the somatic cell or the nucleus of the somatic cell is introduced into an oocyte. The methods of Groups I and II can be carried out independently one from the other.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed milk preparation can be made by the addition of recombinant PDGF produced by means other than the transgenic non-human mammal generated by the process of Group I (e.g., tissue cultures) into a milk preparation.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleic acid of Group IV can be practiced with the patentably distinct method of Group I or Group II.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed milk preparation can be made by the addition of recombinant PDGF produced by means other than the transgenic non-human mammal generated by the process of Group II (e.g., tissue cultures) into a milk preparation.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleic acid of Group IV can be practiced with the patentably distinct method of Group I or Group II.

The products of Groups III and IV are unrelated. The milk preparation of Group III is chemically and structurally distinct from the isolated nucleic acid molecule of Group IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the

examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER